

**IN THE UNITED STATES DISTRICT COURT**  
**FOR THE EASTERN DISTRICT OF TENNESSEE**  
**AT KNOXVILLE**

DONALD K. TURNER )  
11650 Burgess Drive )  
Knoxville, Tennessee 37934 )

Plaintiff )

vs. )

No. \_\_\_\_\_

ALCOA, INC. )  
A Pennsylvania Corporation Whose )  
Agent for Service of Process )  
Within the State of Tennessee Is: )  
CT CORPORATION SYSTEM )  
Suite 2021 )  
800 S Gay Street )  
Knoxville, TN 37929-9710 )

and )

HIGHMARK, INC., d/b/a )  
HIGHMARK BLUE CROSS BLUE )  
SHIELD )  
A Pennsylvania Corporation Whose )  
Agent for Service of Process Is: )  
Thomas L. VanKirk )  
1800 Center Street )  
Camp Hill, PA 17011 )

Defendants )

**COMPLAINT**

Comes now the Plaintiff, Donald K. Turner, by and through his undersigned attorney, and for a cause of action against the Defendants, Highmark, Inc., d/b/a Highmark Blue Cross Blue Shield and Alcoa, Inc., states as follows:

## **I. NATURE OF THE CASE**

1. Donald K. Turner brings this action against the Defendants because of their refusal to cover proton therapy treatment for prostate cancer. Proton therapy is a form of radiation therapy. Like x-ray radiation, proton therapy destroys cancerous cells. Unlike x-ray radiation, proton therapy delivers the majority of radiation at the tumor site and less in the surrounding healthy tissue. Proton therapy allows a higher dose of radiation at the tumor site while reducing the radiation of surrounding organs, which results in more precise cancer control and higher quality of life.

2. Medicare approves proton therapy as a form of treatment for prostate cancer. In addition, Medicare's definition of "experimental treatment" is substantially the same as Alcoa's definition of "experimental treatment" under its plan. Numerous other health care plans pay for proton therapy for treatment of prostate cancer, including other Blue Cross Blue Shield plans.

3. On or about March 2014, Donald K. Turner was diagnosed with prostate cancer. Donald K. Turner was 63 years old, a comparatively young age for diagnosis of prostate cancer. Donald K. Turner had health insurance through his employer, Alcoa, Inc. Donald K. Turner's treating urologist recommended surgery, with a secondary recommendation of IMRT. The urologist advised him that seeds would not work due to a large prostate. Donald K. Turner was advised by his primary care physician that the recommended surgery would have probable side effects including, but not limited to, possible incontinence and impotence. His primary care physician recommended that Donald K. Turner have proton therapy instead of surgery for his prostate cancer. Based

on his physician's recommendation, Donald K. Turner concluded that the treatment that would best control his cancer and give him the highest quality of life was proton therapy.

4. One of the major proton therapy centers, Provision Center for Proton Therapy, is located in Knoxville, Tennessee. The Defendants have denied Donald K. Turner's request for coverage of proton therapy under the theory that it was "experimental." As a result of the denial, Donald K. Turner was forced to self-pay for his proton therapy. Donald K. Turner had proton therapy beginning in May 2014. The proton therapy treatment was successful. As a result of the proton therapy, Donald K. Turner has not had to return to his urologist for any treatment and has none of the probable side effects he would likely have had if had he opted to have surgery or traditional radiation therapy.

## **II. PARTIES**

5. The Plaintiff, Donald K. Turner, is a citizen and resident of Knoxville, Knox County, Tennessee.

6. The Defendant, Alcoa, Inc., is a foreign corporation doing business in Blount County, Tennessee.

7. The Defendant, Highmark, Inc. d/b/a Highmark Blue Cross Blue Shield, ("Highmark"), is a Pennsylvania corporation incorporated under the laws of the State of Pennsylvania, and is licensed under the laws of the State of Tennessee to issue policies of insurance including health insurance.

### **III. JURISDICTION & VENUE**

8. The jurisdiction of this Court attaches under Title 28 U.S.C. §1337 and 29 U.S.C. §1132 § (ERISA §502(e)). Plaintiff's claims "relate to" "employee welfare benefits plan[s]" as defined by ERISA, 29 U.S.C. §1001 *et seq.* and the subject Disability Benefit Plans constitute "plans[s] under ERISA."

9. The Plaintiff has exhausted his administrative appeals with the Defendants. As such, his only course for relief is to file suit as allowed by ERISA. The last appeal denial was dated December 29, 2014 and this suit is filed within 180 days of that date as prescribed by the Defendant's Plan and the ERISA provision. As such, this suit is timely.

### **IV. FACTUAL ALLEGATIONS**

#### ***A. Radiation Therapy for Prostate Cancer***

10. The modern era of radiation therapy for prostate cancer began in the mid-1950's. Technological developments after World War II allowed physicians, for the first time, to make treatment more effective by increasing the radiation dose to the prostate, while simultaneously making treatments safer by reducing the radiation dose to the adjacent rectum and bladder. Later medical linear accelerators produced higher energy x-ray radiation and allowed further improvements in the relative doses to tumors versus normal tissues. Later still, increasingly sophisticated treatment deliver systems, such as conformal techniques, allowed physicians to escalate the radiation doses to the tumor, while reducing the risk of normal tissue injury by minimizing the volume of normal tissue receiving a high dose of radiation.

11. The acceptance of improved techniques allowing for higher radiation doses delivered to tumors with relatively less risk to surrounding tissue has been based solely on the superior normal-tissue-sparing capabilities inherent in these evolving techniques, and not because this superiority was first established as the result of any prospective randomized test. The reason for this is simple. There is no reason a patient would ever opt to unnecessarily irradiate healthy tissue. The deleterious effects of any amount of radiation on human tissue have been well known for nearly a century and are well documented. It would be unnecessary and unethical to perform a randomized trial in which one group of patients received treatment that would gratuitously expose more of their body to radiation.

#### ***B. Proton Therapy***

12. Proton therapy is an effective form of radiation therapy for many types of tumors. It destroys cancer cells by preventing them from dividing and growing, like conventional x-ray radiation. The difference between proton therapy and conventional x-ray radiation is that protons deposit much of their radiation directly in the tumors and then stop. This allows patients to receive higher doses which can be more effective, while reducing damage to healthy tissues that surround the tumors.

13. The physical properties of protons are different from the physical properties of x-rays. Protons are large, positively charged sub-atomic particles that penetrate matter to a finite depth. X-rays are electromagnetic radiation that penetrate completely through tissue. Protons can be conformed to release much of their energy at precise depths so they can target tumors inside the body, depositing much of their radiation exactly at the tumor site. X-rays release their maximum dose of radiation

quickly after penetrating the skin, damaging healthy tissue and organs on their way to the tumors and again as they pass through the body beyond the tumors.

***C. Donald K. Turner's Insurance Coverage***

14. Donald K. Turner is and at all material times has been covered under Alcoa Retiree Health Care Benefits – Choices Program for Eligible Retirees. Donald K. Turner has paid all premiums due on the policy and has performed his obligations arising under the Policy.

15. The Defendants has a copy of the Plaintiff's insurance contract, as such it is not attached thereto.

16. In March 2014, Donald K. Turner was diagnosed with prostate cancer. He was advised of several treatment options by his health care providers. Proton therapy had the best cancer control and the minimum amount of side effects as compared with any other options for treatment of prostate cancer. His treating physician recommended proton therapy for Donald K. Turner and Provision Center for Proton Therapy accepted him for treatment.

17. Donald K. Turner's policy covers "Covered Medical Expenses" as follows:

Covered medical expenses are medically necessary services and supplies, as determined by the claims administrator, that are provided by an eligible provider.

18. Donald K. Turner timely and properly submitted a claim for coverage for proton therapy. By letter dated June 10, 2014, Highmark denied coverage, relying on the determination that this item/service is not eligible for reimbursement because it is a treatment, service, procedure, facility, equipment, drug, service of supply ("intervention")

that has been determined not to be medically effective for the condition being treated, and therefore is considered experimental / investigative if:

- The intervention does not have FDA approval to be marketed for the specific relevant indications); or
- Available scientific evidence does not permit conclusions concerning the effect of the intervention on health outcomes; or
- The intervention is not proven to be as safe or effective in achieving an outcome equal to or exceeding the outcome of alternative therapies; or
- The intervention does not improve health outcomes; or
- The intervention is not proven to be applicable outside the research setting.

19. By letter dated December 29, 2014, the Defendants wrongfully denied payment for the treatment based upon the following:

It is the determination of this reviewer that the proton beam radiation therapy is considered experimental/investigational for the treatment of the enrollee's condition.

The recommended treatment of proton beam radiation therapy has been approved by the Food and Drug Administration (FDA) for the treatment of cancers. However, the medical and scientific evidence does not demonstrate that the expected benefits of the requested health care service are more likely to be beneficial to the enrollee than any available standard health care service.

Proton beam radiation therapy is not considered a standard of care treatment option for prostate carcinoma. There is no adequate medical literature published in peer reviewed journals supporting its use as equivalent for better or safer than standard photon radiation therapy such as 3D conformal or IMRT. National Comprehensive Cancer Network (NCCN) guidelines (1) state the investigational nature of proton beam radiation therapy for prostate carcinoma at this time. More randomized studies are needed to support its use as safe and effective for early state prostate carcinoma.

20. The Defendants previously incorrectly denied coverage based upon a Policy Highmark referred to as R-18. This policy provides:

"...Proton beam therapy is considered eligible when performed for the following indications:

- Chordomas and chondrosarcomas of the base of the skull or spine;

- Melanoma of the uvea tract (iris, ciliary body, and choroid). There must be no evidence of extrascleral extension. The diameter of the tumor must not exceed 24 mm and the height must not exceed 14 mm;
- Hepatocellular carcinoma;
- Pediatric brain tumors such as posterior fossa tumors, optic pathway tumors and brainstem lesions (from the report of ASTRO's emerging technology committee);
- Pediatric CNS tumors; and
- Pediatric spinal tumors.

All other applications or uses of proton beam radiation therapy are considered experimental/investigational and ineligible for payment. Currently published medical literature does not provide sufficient documentation to permit conclusions concerning the effect on health outcomes. This modality remains an area of research . . . “

21. The policies of the Defendants and in particular the denial of the claim of Donald K. Turner is incorrect and an abuse of discretion by the Defendants. The treatment prescribed is not experimental and has shown to be much more effective with fewer side effects than other therapies. The Defendants' decision and policies are arbitrary and capricious.

#### ***D. Proton Therapy and Prostate Cancer***

22. Proton beam therapy is one type of external beam radiation therapy. Proton beams undergo minimal lateral scattering in the patient and deposit their energy at a finite and adjustable depth, thus minimizing damage to healthy tissue near the cancerous tissue. Protons deposit their energy over a very small area, which is called the Bragg peak. The Bragg peak can be used to target high doses of proton beam therapy to a tumor while doing less damage to normal tissues in front of and behind the tumor. In addition, proton beam therapy can be administered while minimizing the dose delivered to surrounding healthy tissue. Proton beams enable patients to tolerate higher total doses of radiation compared with photon (x-rays) radiation. Protons have a dose distribution



that spares more healthy tissue than the equivalent dose of photon-based radiation, including intensity modulated radiation therapy (IMRT). Proton therapy can reduce the dose to healthy tissue, in some cases by more than half, compared to IMRT. Proton therapy may be used alone or in combination with photon radiation therapy. Like conventional radiation therapy, proton therapy treatments may take anywhere from a few days or up to several weeks, depending on the tumor to be effective. When treating a tumor, protons compared to x-rays deliver:

- More energy to the tumor;
- Less energy to healthy tissue proximal to the tumor; and
- Little to no energy beyond the distal edge of the tumor.

The intent of proton beam therapy is to definitively treat tumors with a curative intent. Less frequently, proton beam therapy may provide relief of symptoms caused by tumors in sensitive sites where conventional radiotherapy techniques are not feasible. Proton beam therapy is particularly advantageous when relatively high radiation doses are needed to achieve optimal tumor control, when doses to normal tissues need to be minimized, and other treatment techniques are not feasible due to decreased probabilities for tumor control and/or an elevated risk of side effects.

#### ***E. Efficacy of Proton Therapy is Well-Established***

23. The efficacy and safety of proton therapy for prostate cancer is well established. Loma Linda University has published long-term follow-up of their prospective experience of treating prostate cancer with protons since 1991. Since then, many other groups have published reports on their experience using protons.

#### ***F. Evidence for Dose Escalation***

24. There are 4 prospective randomized trials proving that dose-escalation in prostate cancer leads to better cure rates, and these 4 trials form the crux of proton treatment strategies in radiation therapy today. Three trials used X-ray therapy while the fourth trial used X-ray therapy combined with protons. These trials were from the same era and used similar planning and delivery techniques. All 4 trials had the same conclusion: higher radiation doses lead to higher cure rates. Three of the trials also found that higher doses also led to markedly higher complication rates. PROG 95-09, the one trial to incorporate protons, did not see a higher complication rate and, in fact, had complication rates 80% lower than the other 3 trials. PROG 9509 also had the highest cure rates, by 14% over any other trial. The largest IMRT series for prostate cancer with greater than 5 years follow-up was published by Memorial Sloan Kettering in 2006 and updated in 2010. It is a retrospective, single-institution study and thus subject to selection bias and other pitfalls of retrospective reviews. Thus, the prospective data mentioned above represents a superior level of evidence on which to base medical decision-making.

#### ***G. Proton Therapy Decreases the Risk of Long-Term Toxicity***

25. Proton therapy is considered a superior treatment option compared to x-ray treatment options including IMRT, Tomotherapy and Cyber Knife. Compared to IMRT, protons deliver less than half of the radiation dose to surrounding normal tissues. There is a good target conformality for both IMRT and protons. However, the non-target dose is far higher with IMRT than it is for protons. This excess radiation does not benefit the patient in any way and increases the rate of toxicity.

It is clear that protons deliver less radiation dose to normal tissues and on average, protons decrease rectal dose by 59%. Recently published data has proven that the entire rectal DVH predicts for a late rectal toxicity, but the V32.4 and V70 points have been shown in 2 different papers from M.D. Anderson Cancer Center to be particularly predictive of late complications. The doses at both of these inflection points are markedly lowered with the use of proton therapy.

26. Proton radiotherapy allows for dose escalation to provide better local control and cause specific survival of the surrounding healthy tissue when treating prostate cancer. This dose escalation comes at no increased damage to surrounding normal tissues and actually provides a more tolerable dose distribution. The risk of developing a second cancer is substantially less for patients who undergo proton therapy as compared to less advanced treatments such as radioactive seeds and X-ray therapy.

27. The Defendants rely upon Highmark Medical Policy Bulletin R-18 to deny coverage as experimental. Their conclusion that proton beam therapy is experimental is inconsistent with the description of proton beam radiation therapy contained in Bulletin R-18. Said description states:

Proton beam radiation therapy is a treatment modality that delivers high dose radiation to a localized site. This type of radiation, also called particulate radiation, uses charged particles known as protons, which is different from conventional electron beam (or photons) radiation therapy because it has several unique properties. Proton ions or particles slow down faster than photons. As they pass through tissue, they deposit more energy at precise depths as they slow down, culminating in a peak (called a Bragg peak). This method delivers the majority of radiation to the target site with minimal scatter, sparing surrounding or adjacent normal tissues.

This description of proton beam radiation therapy is exactly the reason that the Plaintiff chose this form of treatment. In particular, the Plaintiff chose proton therapy because as

stated in Bulletin R-18: "This method delivers the majority of radiation to the target site with minimal scatter, sparing surrounding or adjacent normal tissue."

28. At one time, proton treatment for prostate cancer was experimental. It is now a well-established successful treatment for prostate cancer. The Defendants have failed to properly update their policies concerning proton treatment to be consistent with recent medical studies and advancements. Proton treatment for prostate cancer is clearly not experimental as it is covered by numerous health insurance carriers, including Medicare that also exclude "experimental" treatment. The Defendants and the Administrator have abused their discretion in denying the claim of the Plaintiff and their decision is arbitrary and capricious.

29. Further, the Defendants in Bulletin R-18 have acknowledged that proton therapy is a superior form of cancer treatment with less side effects to the patient. As such, the Defendants and the Administrator have abused their discretion in falsely claiming that proton therapy for treatment of prostate cancer is experimental and their decision is arbitrary and capricious. Further, such a policy puts the employees covered by insurance coverage provided by the Defendants at risk of not having successful treatment of their cancer and having significant disabling side effects. Such a dangerous policy, which is inconsistent with their own definition of proton therapy contained in Bulletin R-18 and such policy is arbitrary and capricious.

## V. CLAIMS

30. Donald K. Turner asserts claims against the Defendants for (1) breach of contract and (2) the bad faith of the Defendants for denying the claim.

31. Donald K. Turner seeks all benefits to which he is entitled under the coverage referenced herein, and further consequential and statutory damages in an amount to be proven at trial.

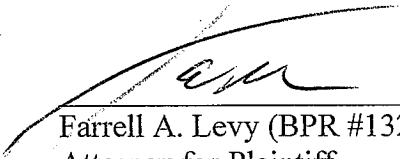
**VI. PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for the following relief;

- I. Damages in an amount to be proven at trial;
- II. Prejudgment and post-judgment interest;
- III. Plaintiff's costs and attorney's fees; and
- IV. Such other and further general relief as the Court deems just and equitable.

DATED this 26<sup>th</sup> day of June 2015.

/s/ Farrell A. Levy  
Farrell A. Levy (BPR #1326)  
Attorney for Plaintiff

  
Farrell A. Levy (BPR #1326)  
Attorney for Plaintiff

McDONALD, LEVY & TAYLOR  
Attorneys at Law  
10805 Kingston Pike, Suite 200  
Knoxville, TN 37934  
Phone: (865) 966-4343